



Application No.: 09/720,940
Appeal Brief dated February 21, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Re: Application of: OSCHMANN et al.
Serial No.: 09/720,940 Confirmation No.: 8398
Filed: 01/02/2001
For: **WATER-SOLUBLE NATIVE DRY PLANT EXTRACT,
IN PARTICULAR GINKGO BILOBA EXTRACT WITH
A HIGH CONTENT OF TERPENOID
AND FLAVONGLYCOSIDES**
Art Unit: 1616
Examiner: SABIHA QAZI
Customer No.: 23280
Atty. Docket: 113.1009

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

February 20, 2006

APPELLANTS' BRIEF UNDER 37 C.F.R. § 41.37

Sir:

Appellants submit this brief for the consideration of the Board of Patent Appeals and Interferences (the "Board") in support of their appeal of the Final Rejection dated June 21, 2005 in this application. The statutory fee of \$500.00 is paid concurrently herewith.

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1. REAL PARTY IN INTEREST

The real party in interest is Dr. Willmar Schwabe GmbH & Co., a German company with offices in Karlsruhe, Germany.

2. RELATED APPEALS AND INTERFERENCES

Appellants, their legal representatives, and assignee are not aware of any appeal, interference or judicial proceeding that directly affects, will be directly affected by, or will have a bearing on the Board's decision in this appeal.

3. STATUS OF CLAIMS

Claims 11 to 18 are pending and have been finally rejected as per the Final Office Action dated July 13, 2005. Claim 25 is withdrawn.

The rejection to claims 11 to 18 thus is appealed. A copy of appealed claims 11 to 18 is attached hereto as Appendix A.

4. STATUS OF AMENDMENTS AFTER FINAL

No amendments to claims were filed after the final rejection. An advisory action was issued on November 10, 2005. A Notice of Appeal was filed on December 8, 2005 and received by the U.S.P.T.O. on December 12, 2005.

5. SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 11 recites a water-soluble, native dry extract consisting essentially of Ginkgo biloba plant part constituents (see specification page 4, lines 20 to 25 for example), wherein the extract is produced by ultrafiltration (see page 7, lines 9 to 10) using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons (see page 7, lines 10 to 13) and wherein the extract lacks any solubilization agents (see specification page 4, line 25).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 11 to 18 should be rejected under obviousness-type double patenting over claim 1 of U.S. Patent No. 6,328,999. Whether claims 11 to 18 should be rejected under obviousness-type double patenting over claims 1 to 14 of U.S. Patent No. 5,512,286.

Whether claims 11 to 18 should be rejected under obviousness-type double patenting over claims 1 to 25 of U.S. Patent No. 6,399,099. Whether claims 11 to 18 should be rejected under obviousness-type double patenting over claims 1 to 4 of U.S. Patent No. 5,399,348. Whether claims 11 to 18 should be rejected under obviousness-type double patenting over claim 12 of U.S. Patent No. 5,322,688. Whether claim 15 should be rejected under 35 U.S.C. 102(b) as anticipated by Japanese 279300. Whether claim 15 should be rejected under 35 U.S.C. 102(b) as anticipated by Liu. Whether claims 11 to 18 should be rejected under 35 U.S.C. 103 as unpatentable over Japanese 279300. Whether claims 11 to 18 should be rejected under 35 U.S.C. 103 as unpatentable over Liu.

7. ARGUMENTS

Double Patenting Rejections

A. U.S. Patent No. 6,328,999

Claims 11 to 18 were rejected under obviousness-type double patenting over claim 1 of U.S. Patent No. 6,328,999.

Claim 1 of the '999 patent recites a ginkgo biloba leaf extract having certain percentages of constituents.

Claim 11 of the present application recites a "water-soluble, native dry extract consisting essentially of Ginkgo biloba plant part constituents, wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons and wherein the extract lacks any solubilization agents."

The present rejections all center around whether the limitation "wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons" carries any weight or not. It is respectfully submitted that the present inventive extract necessary consists essentially of constituents having an average molecular cut off weight of less than 10000 Daltons, as the extract is formed by the claimed ultrafiltration. As stated in the specification at page 9, line 1 et seq., this ultrafiltration removes or deactivates components which "impede the water solubility of dry extracts" and results in a novel extract with excellent water solubility properties.

In other words, as clear from the specification, the resultant product created by the ultrafiltration is different and novel over non-ultrafiltered Ginkgo leaf extracts, which contain particles much larger than 10000 Daltons, and do not consist essentially of the ultrafiltered particles as recited in claim 1. See MPEP 2113: "if the manufacturing steps impart

distinctive structural characteristics to the final product” the claim limitation should be given weight.

Claim 1 of the ‘999 patent does not teach or show “wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons” as recited in claim 11 nor is there any indication or assertion that an extract produced by ultrafiltration using such a filter size would have been obvious to one of skill in the art.

Withdrawal of the rejection is respectfully requested.

B. U.S. Patent No. 5,512,286

Claims 11 to 18 were rejected under obviousness-type double patenting over claims 1 to 14 of U.S. Patent No. 5,512,286.

Claims 1 to 14 of the ‘286 patent do not teach or show “wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons” as recited in claim 11 nor is there any indication or assertion that an extract produced by ultrafiltration using such a filter size would have been obvious to one of skill in the art.

Withdrawal of the rejection is respectfully requested.

C. U.S. Patent No. 6,399,099

Claims 11 to 18 were rejected under obviousness-type double patenting over claims 1 to 25 of U.S. Patent No. 6,399,099.

Claims 1 to 25 of the ‘099 patent do not teach or show “wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons” as recited in claim 11 nor is there any indication or assertion that an extract produced by ultrafiltration using such a filter size would have been obvious to one of skill in the art.

Withdrawal of the rejection is respectfully requested.

D. U.S. Patent No. 5,399,348

Claims 11 to 18 were rejected under obviousness-type double patenting over claims 1 to 4 of U.S. Patent No. 5,399,348.

Claims 1 to 4 of the ‘348 patent do not teach or show “wherein the extract is produced

by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons” as recited in claim 11 nor is there any indication or assertion that an extract produced by ultrafiltration using such a filter size would have been obvious to one of skill in the art.

Withdrawal of the rejection is respectfully requested.

E. U.S. Patent No. 5,322,688

Claims 11 to 18 were rejected under obviousness-type double patenting over claim 12 of U.S. Patent No. 5,322,688.

Claim 12 of the ‘688 patent does not teach or show “wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons” as recited in claim 11 nor is there any indication or assertion that an extract produced by ultrafiltration using such a filter size would have been obvious to one of skill in the art.

Withdrawal of the rejection is respectfully requested.

35 U.S.C. 102(b) Rejections

A. Japanese 279300

Claim 15 was rejected under 35 U.S.C. 102(b) as anticipated by Japanese 279300.

JP 279300 is discussed in the present specification and discloses Gingko extracts in general.

Claim 15 recites the dry extract of claim 11, wherein the extract is a partially purified dry extract partially purified by removal of extraction solvents prior to the ultrafiltration.

The Final Office Action seems to admit that claim 11, on which claim 15 depends does not show each feature of claim 11, as claim 11 is rejection under 35 U.S.C. 103.

However, for some reason claim 15 is rejected as anticipated even though it depends on claim 11.

It is respectfully submitted that JP 279300 does not teach or show “wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons” as recited in claim 11 and thus the anticipation rejection

Nor has any product produced by such ultrafiltration been asserted.

Withdrawal of the anticipation rejection is respectfully requested.

B. Liu

Claim 15 was rejected under 35 U.S.C. 102(b) as anticipated by Liu.

Liu discloses Gingko extracts in general.

Claim 15 recites the dry extract of claim 11, wherein the extract is a partially purified dry extract partially purified by removal of extraction solvents prior to the ultrafiltration.

The Final Office Action seems to admit that claim 11, on which claim 15 depends does not show each feature of claim 11, as claim 11 is rejection under 35 U.S.C. 103.

However, for some reason claim 15 is rejected as anticipated even though it depends on claim 11.

It is respectfully submitted that Liu does not teach or show “wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons” as recited in claim 11 and thus the anticipation rejection

Nor has any product produced by such ultrafiltration been asserted.

35 U.S.C. 103 Rejections

A. Japanese 279300

Claims 11 to 18 were rejected under 35 U.S.C. 103 as unpatentable over Japanese 279300.

JP279300 does not teach or show “wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons” as recited in claim 11 nor is there any indication or assertion that an extract produced by ultrafiltration using such a filter size would have been obvious to one of skill in the art.

Withdrawal of the rejection is respectfully requested.

B. Liu

Claims 11 to 18 were rejected under 35 U.S.C. 103 as unpatentable over Liu.

Liu does not teach or show “wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons” as recited in claim 11 nor is there any indication or assertion that an extract produced by ultrafiltration using such a filter size would have been obvious to one of skill in the art.

Withdrawal of the rejection is respectfully requested.

CONCLUSION

It is respectfully submitted that the application is in condition for allowance.
Favorable consideration of this appeal brief is respectfully requested.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
William C. Gehris, Reg. No. 38,156

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, NY 10018
Tel: (212) 736-1940
Fax: (212) 736-2427



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APPENDIX A:

APPEALED CLAIMS 11 to 18 OF U.S. APPLICATION SERIAL NO. 09/720,940

Claim 11: A water-soluble, native dry extract consisting essentially of Ginkgo biloba plant part constituents, wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons and wherein the extract lacks any solubilization agents.

Claim 12: The dry extract of claim 11, wherein the plant part constituents comprise Ginkgo biloba leaves.

Claim 13: The dry extract of claim 12, wherein the plant part constituents comprise terpenlactones and flavonglycosides, a higher percentage content of terpenlactones and flavonglycosides being present in the extract as compared to the Ginkgo biloba leaves from which the extract is extracted.

Claim 14: The dry extract of claim 11, wherein the extract is a dried raw extract.

Claim 15: The dry extract of claim 11, wherein the extract is a partially purified dry extract partially purified by removal of extraction solvents prior to the ultrafiltration.

Claim 16: The dry extract of claim 15, wherein the dry extract is subjected prior to the ultrafiltration to adsorption and desorption processes and extraction with n-butanol-type purification procedures.

Claim 17: The dry extract of claim 11 comprising a content of:

- at least 20 % flavonglycosides by mass,
- at least 5 % terpenlactones by mass, and
- at most 5 parts per million (ppm) ginkgolic acids.

Claim 18: The dry extract of claim 11 comprising a content of:

- at least 22 - 27 % flavonglycosides by mass,
- at least 5 - 7 % terpenlactones by mass,
- at least 2.8 - 3.4 % ginkgolides A, B, C by mass,
- at least 2.6 - 3.2 % bilobalide by mass, and
- at most 5 ppm of ginkgolic acids.

APPENDIX B

Evidence Appendix under 37 C.F.R. §41.37 (c) (ix):

No evidence pursuant to 37 C.F.R. §§1.130, 1.131 or 1.132 and relied upon in the appeal has been submitted by appellants or entered by the examiner.

APPENDIX C

Related proceedings appendix under 37 C.F.R. §41.37 (c) (x):

As stated in “2. RELATED APPEALS AND INTERFERENCES” of this appeal brief, appellants, their legal representatives, and assignee are not aware of any appeal or interference that directly affects, will be directly affected by, or will have a bearing on the Board's decision in this appeal.